

REMARKS

This Amendment is submitted in response to the final Office Action mailed on January 30, 2008. No fee is due in connection with this Amendment. The Director is authorized to charge any fees which may be required, or to credit any overpayment to Deposit Account No. 02-1818. If such a withdrawal is made, please indicate the Attorney Docket No. 112701-746 on the account statement.

Claims 1-4, 6-9 and 11-26 are pending in this application. Claims 17-21 were withdrawn from consideration and Claims 5 and 10 were previously canceled without prejudice or disclaimer. In the Office Action, Claims 16 and 25 are rejected under 35 U.S.C. §112. Claims 1-4, 6, 8-9, 11-16, 22 and 24-26 are rejected under 35 U.S.C. §102. Claims 1-4, 6-9, 11-16 and 23-26 are rejected under 35 U.S.C. §103. In response, Claims 1, 9, 14-16, 22 and 24-26 have been amended. These amendments do not add new matter. In view of the amendments and/or for at least the reasons set forth below, Applicants respectfully submit that the rejections should be withdrawn.

Claims 1, 9, 15, 22, 24 and 26 have been amended for clarification purposes to correctly the spelling of the term “cryptoxanthin.” The claims had previously recited the term as “cyrptoxanthin.” These amendments do not add new matter. These amendments are supported in the Specification, for example, at page 5, lines 29-31.

In the Office Action, Claims 16 and 25 are rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite. The Examiner asserts that the limitation “the content” in both Claims 16 and 25 lacks sufficient antecedent basis. See, Office Action, page 2, lines 18-21. In response, Applicants have amended Claims 14, 16 and 25 for clarification purposes. With respect to Claims 14 and 25, currently amended Claim 14 recites, in part, an oral composition wherein the primary composition comprises between about 0.001 and 100% of the oral composition. Similarly, currently amended Claim 25 recites, in part, an oral composition wherein the primary composition comprises between about 10 and 50% of the oral composition. These amendments are supported in the Specification, for example, at page 8, lines 19-22 and 24-27. Claim 9 from which Claims 14 and 25 depend recites, in part, an oral composition comprising a primary composition. Thus, Applicants respectfully submit that Claims 14 and 25 have sufficient antecedent basis for the primary composition.

With respect to Claim 16, currently amended Claim 16 recites, in part, a cosmetic composition wherein the primary composition comprises between about 10⁻¹⁰ and 10% of the cosmetic composition. This amendment does not add new matter. This amendment is supported in the Specification, for example, at page 10, lines 6-9. Claim 15 from which Claim 16 depends recites, in part, a cosmetic composition comprising a primary composition. Therefore, Applicants respectfully submit that currently amended Claim 16 has sufficient antecedent basis for the primary composition.

Accordingly, Applicants respectfully request that the rejection of Claims 16 and 25 under 35 U.S.C. §112, second paragraph, be withdrawn.

In the Office Action, Claims 1-4, 6, 8-9, 11-15, 22 are rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,965,183 to Hartal et al. (“*Hartal*”). For at least the reasons set forth below, Applicants respectfully submit that the rejection should be withdrawn

Independent Claims 1, 9 and 15 recite, in part, a composition comprising at least one carotenoid-containing material, enriched in cis-isomer of the carotenoid compound, wherein the carotenoid compound is selected from the group consisting of lycopene, xeaxanthine, beta-cryptoxanthin, capsanthine, canthaxanthine, lutein, phytofluene, phytoene, and combinations thereof. Similarly, independent Claim 22 recites, in part, a method for improving skin health comprising the step of administering to a patient in need of improved skin health at least one carotenoid-containing material, enriched in cis-isomer of the carotenoid compound, wherein the carotenoid compound is selected from the group consisting of lycopene, xeaxanthine, beta-cryptoxanthin, capsanthine, canthaxanthine, lutein, phytofluene, phytoene, and combinations thereof. Applicants respectfully submit that *Hartal* fails to disclose each and every element of the present claims.

Applicants submitted herewith an Affidavit under 37 C.F.R. §1.132 (“*Affidavit*” attached hereto as Exhibit A) that demonstrates the deficiencies of the prior art with respect to the present claims. As supported by the *Affidavit*, and as taught by Applicants’ specification, a carotenoid isolated or enriched from a natural source such as a plant or animal is distinguishable from a carotenoid-containing material enriched in cis-isomer of the carotenoid compound. The isolated or enriched carotenoid must be subjected to further physical or chemical treatment in order to increase its content of *cis*-isomers.

For example, a carotenoid-containing material enriched in *cis*-isomer of the carotenoid compound in accordance with the present claims provides a better bioavailability and/or bioefficacy of the carotenoid compound than the carotenoid compound alone. See, Specification, page 2, lines 1-4 and 18-22; page 7, lines 5-7. Specifically, the carotenoid-containing material enriched in *cis*-isomers is more soluble in lipids and organic solvents, is less prone to crystallization, and has a lower tendency to aggregate. See, Specification, page 3, lines 5-10.

In contrast, Applicants respectfully submit that *Hartal* fails to disclose or suggest every element of the present claims. For example, *Hartal* fails to disclose or suggest a carotenoid-containing material enriched in *cis*-isomer of the carotenoid compound as required, in part, by currently amended independent Claims 1, 9, 15 and 22. Instead, *Hartal* only discloses, at best, a carotenoid isolated or enriched from plants, animals or other natural sources.

As supported by the *Affidavit*, a carotenoid-containing material enriched in *cis*-isomer of the carotenoid compound is completely distinguishable from a carotenoid isolated or enriched from plants, animals or other natural sources. The carotenoid-containing materials of the present claims are carotenoid compounds such as lycopene, xeaxanthine, beta-cryptoxanthin, capsanthine, canthaxanthine, lutein, phytofluene, phytoene that are obtained, extracted, enriched or purified from a plant or vegetable material, a microorganism, a yeast or a product of animal origin. See, Specification, page 4, lines 17-19; page 5, lines 29-31. The *cis*-isomer content of such enriched or extracted carotenoid compounds is low. See, Specification, page 5, lines 20-22. Thus, the carotenoid compounds enriched or extracted from plants, animals or other natural sources must be subjected to further treatment in order to enrich their *cis*-isomer content, including microwave irradiation and/or solubilization followed by phase separation. See, Specification, page 4, lines 19-20; page 6, lines 17-30. Such treatment increases the *cis*-isomer content of the carotenoid up to at least 20 percent. See, Specification, page 7, lines 1-2.

As further illustrated by the *Affidavit*, carotenoids are known to have beneficial effects such as alleviating chronic diseases. See, Specification, page 1, lines 11-13. However, the carotenoids enriched or extracted from plants, animals or other natural sources are not sufficiently bioavailable. See, Specification, page 1, lines 15-17. Thus, the beneficial effects of such carotenoids are not fully realized when the carotenoid is merely extracted or enriched from natural sources.

Further, the *Affidavit* also illustrates that the bioavailability and/or bioefficacy of carotenoid compounds is increased by enriching the *cis*-isomer content of such carotenoid compounds. See, Specification, page 2, lines 1-4 and 18-22. Unlike carotenoids isolated or enriched from natural sources, carotenoids enriched in *cis*-isomer content are more soluble in lipids, less prone to crystallization, and have a lower tendency to aggregate. See, Specification, page 3, lines 5-10. In contrast, carotenoids isolated or enriched from natural sources are insufficiently bioavailable. See, Specification, page 1, lines 15-17. The bioavailability of such carotenoids is increased only by subjecting the isolated or enriched carotenoid compounds to further physical or chemical treatment to increase the *cis*-isomer content of such compounds. See, Specification, page 5, lines 25-27; page 6, lines 17-30. For at least the reasons discussed above, Applicants respectfully submit that *Hartal* fails to disclose a carotenoid-containing material enriched in *cis*-isomer of the carotenoid compound as required, in part, by the present claims.

Accordingly, Applicants respectfully request that the rejection of Claims 1-4, 6, 8-9, 11-15, 22 under 35 U.S.C. §102 to *Hartal* be withdrawn.

In the Office Action, Claims 1-4, 6, 8-9 and 11-14 are rejected under 35 U.S.C. §102(b) as anticipated by U.S. Patent No. 6,329,557 B1 to Rodriguez et al. (“Rodriguez”). For at least the reasons set forth below, Applicants respectfully submit that the cited reference fails to disclose or suggest every element of the present claims.

For example, *Rodriguez* fails to disclose or suggest a carotenoid-containing material enriched in *cis*-isomer of the carotenoid compound as required, in part, by currently amended independent Claims 1 and 9. As acknowledged by the Examiner, *Rodriguez* merely discloses, at best, carotenoids isolated or extracted from plants, crustaceans, birds, algae and bacteria. See, Office Action, page 4, lines 5-7. Nowhere does *Rodriguez* disclose carotenoids enriched in *cis*-isomers.

As supported by the *Affidavit*, carotenoids isolated from natural sources such as plants, animals and bacteria are distinguishable from carotenoids enriched in their *cis*-isomers. Contrary to the Examiner’s assertion, isolation of carotenoids alone does not necessarily lead to the enrichment of *cis* forms of carotenoids in accordance with the present claims. See, Office Action, page 4, lines 10-13. The isolated carotenoids require further physical or chemical

treatment to enrich the *cis*-isomer content of the carotenoid compound. See, Specification, page 6, lines 17-30. Thus, *Rodriguez* fails to disclose or suggest a carotenoid-containing material enriched in *cis*-isomer of the carotenoid compound as required, in part, by the present claims.

Accordingly, Applicants respectfully request that the rejection of Claims 1-4, 6, 8-9 and 11-14 under 35 U.S.C. §102 to *Rodriguez* be withdrawn.

In the Office Action, Claims 1-4, 6, 8-9, 11-16, 22 and 24-26 are rejected under 35 U.S.C. §102(b) as anticipated by U.S. Patent No. 5,310,554 to Haigh ("Haigh"). For at least the reasons set forth below, Applicants respectfully submit that the cited reference fails to disclose or suggest every element of the present claims.

For example, *Haigh* fails to disclose or suggest a carotenoid-containing material, enriched in *cis*-isomer of the carotenoid compound, wherein the carotenoid compound is selected from the group consisting of lycopene, xeaxanthine, beta-cryptoxanthin, capsanthine, canthaxanthine, lutein, phytofluene, phytoene, and combinations thereof as required, in part, by currently amended independent Claims 1, 9, 15, 22, 24 and 26. As acknowledged by the Examiner, *Haigh* only discloses beta-carotenes purified from plants. See, Office Action, page 4, lines 21-23; page 5, lines 1-20. Nowhere does *Haigh* disclose carotenoids selected from the group consisting of lycopene, xeaxanthine, beta-cryptoxanthin, capsanthine, canthaxanthine, lutein, phytofluene, phytoene, and combinations thereof.

The Examiner asserts that *Haigh* teaches at least one carotenoid enriched in *cis*-isomer content of the carotenoid compound. See, Office Action, page 5, lines 18-20. However, the only carotenoid compound disclosed by *Haigh* is beta-carotene. In contrast, the present claims recite, in part, a carotenoid compound selected from the group consisting of lycopene, xeaxanthine, beta-cryptoxanthin, capsanthine, canthaxanthine, lutein, phytofluene, phytoene, and combinations thereof. Since beta-carotene is not one of the enumerated carotenoid compounds, *Haigh* fails to disclose or suggest a carotenoid-containing material, enriched in *cis*-isomer of the carotenoid compound, wherein the carotenoid compound is selected from the group consisting of lycopene, xeaxanthine, beta-cryptoxanthin, capsanthine, canthaxanthine, lutein, phytofluene, phytoene, and combinations thereof as required, in part, by the present claims.

Accordingly, Applicants respectfully request that the rejection of Claims 1-4, 6, 8-9, 11-16, 22 and 24-26 under 35 U.S.C. §102 to *Haigh* be withdrawn.

In the Office Action, Claims 1-4, 6-9, 11-16 and 23-26 are rejected under 35 U.S.C. §103(a) as unpatentable over *Haigh*. The Examiner asserts that using oleoresin composition to treat skin and combining the claimed ingredients into a single composition are obvious modifications of *Haigh*. See, Office Action, page 7, lines 15-21; page 8, lines 1-6. However, as discussed previously, *Haigh* fails to disclose or suggest a carotenoid-containing material, enriched in *cis*-isomer of the carotenoid compound, wherein the carotenoid compound is selected from the group consisting of lycopene, xeaxanthine, beta-cryptoxanthin, capsanthine, canthaxanthine, lutein, phytofluene, phytoene, and combinations thereof as required, in part, by currently amended independent Claims 1, 9, 15, 22, 24 and 26. Thus, Applicants respectfully submit that *Haigh* fails to disclose or suggest every element of the present claims.

Accordingly, Applicants respectfully request that the rejection of Claims 1-4, 6-9, 11-16 and 23-26 under 35 U.S.C. §103(a) to *Haigh* be withdrawn.

For the foregoing reasons, Applicants respectfully request reconsideration of the above-identified patent application and earnestly solicit an early allowance of same. In the event there remains any impediment to allowance of the claims that could be clarified in a telephonic interview, the Examiner is respectfully requested to initiate such an interview with the undersigned.

Respectfully submitted,

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